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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,313	10/06/2003	Usha Kasid	GTU-06-1183WO-US	5935

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EXAMINER	
BOWMAN, AMY HUDSON	
ART UNIT	**PAPER NUMBER**
1635	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	02/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/680,313	KASID ET AL.	
	Examiner	Art Unit	
	Amy H. Bowman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/31/2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, 9, 11 and 16-18, drawn to an isolated nucleic acid molecule, a recombinant vector comprising the nucleic acid molecule, a recombinant host cell comprising the recombinant vector, and an epitope-bearing portion of the polynucleotide encoded by the sequence, classified in class 536, subclass 23.1 and class 435, subclass 320.1.

II. Claim 8, drawn to a method of making a recombinant vector, classified in class 435, subclass 91.4.

III. Claim 10, drawn to a method of making a recombinant host cell, classified in class 435, subclass 455.

IV. Claim 12, drawn to a recombinant method of producing a polypeptide, classified in class 435, subclass 70.1.

V. Claims 13-15, drawn to an isolated polypeptide, classified in class 530, subclass 350.

VI. Claims 19 and 20, drawn to an isolated antibody that binds specifically to a polypeptide, classified in class 530, subclass 387.1.

VII. Claims 21 and 22, drawn to a method of modulating apoptosis or proliferation of a cancer cell comprising regulating expression of SHINC-1 in a mammalian cell, classified in class 514 subclass 44.

VIII. Claims 23 and 24, drawn to an antisense oligonucleotide that inhibits the expression of SHINC-1 in a mammalian cell, classified in class 536, subclass 24.5.

IX. Claims 25, 30 and 31, drawn to a method comprising administering an antisense oligonucleotide that inhibits SHINC-1 expression, classified in class 514, subclass 44. **Election of this group requires a further election of a single species of cancer types from claim 31, as explained below.**

X. Claims 25, 30 and 31, drawn to a method comprising administering a ribozyme that inhibits SHINC-1 expression, classified in class 514, subclass 44. **Election of this group requires a further election of a single species of cancer types from claim 31, as explained below.**

XI. Claims 26 and 34, drawn to a method comprising administering an antibody that specifically binds SHINC-1, classified in class 424, subclass 93.1.

XII. Claims 27 and 28, drawn to a method comprising detecting levels of SHINC-1 expression and correlating said levels of expression to the presence or absence of cancer, wherein the method is effected by using a cDNA that hybridizes to SHINC-1 mRNA, classified in class 436, subclass 94.

XIII. Claims 27 and 29, drawn to a method comprising detecting levels of SHINC-1 expression and correlating said levels of expression to the

presence or absence of cancer, wherein the method is effected by using an antibody that specifically binds SHINC-1, classified in class 424, subclass 93.1.

XIV. Claims 32 and 33, drawn to a method of treating a condition characterized by SHINC-1 underexpression comprising administering an agent that promotes SHINC-1 expression, classified in class 514, subclass 44.

XV. Claim 34, drawn to a method for inhibiting cancer cell proliferation and/or metastasis in a cancer patient comprising administering a ribozyme in combination with radio therapy, classified in class 514, subclass 44.

XVI. Claim 34, drawn to a method for inhibiting cancer cell proliferation and/or metastasis in a cancer patient comprising administering an antisense oligonucleotide in combination with radio therapy, classified in class 514, subclass 44.

XVII. Claim 34, drawn to a method for inhibiting cancer cell proliferation and/or metastasis in a cancer patient comprising administering chemotherapy, classified in class 424, subclass 93.1.

XVIII. Claim 34, drawn to a method for inhibiting cancer cell proliferation and/or metastasis in a cancer patient comprising administering a hormone, classified in class 424, subclass 93.1.

XIX. Claim 34, drawn to a method for inhibiting cancer cell proliferation and/or metastasis in a cancer patient comprising administering a biological anticancer agent, classified in class 424, subclass 93.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the method of making a recombinant vector can be used to make another materially different vector, rather than the vector of group I. To search for one of the methods would not necessarily return art against either of the other methods. Therefore, to search more than one of the inventions in the same application presents an undue search and examination burden.

Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the method of making a recombinant host cell can be used to make another materially different host cell, rather than the host cell of group I. To search for one of the methods would not necessarily return art against either of the other methods. Therefore, to search more than one of the inventions in the same application presents an undue search and examination burden.

Inventions II-IV, VII, and IX-XIX are each unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have

different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are each directed to unrelated methods, each having separate and distinct steps. To search for one of the methods would not necessarily return art against either of the other methods and the methods do not render each other obvious. Therefore, to search more than one of the inventions in the same application presents an undue search and examination burden.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the host cell can be used in another method other than to produce a polypeptide, such as for experimental assays or probe for a particular sequence of interest in the cell.

The invention of groups I, V, VI and VIII are each unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together and have different designs. The inventions are drawn to separate and distinct molecules, containing no common structural core. To search for one of the inventions would not necessarily return art against either of the other inventions. Therefore, to search more than one of the inventions in the same application presents an undue search and examination burden.

The invention of groups II and III are unrelated to the invention of group V. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together and have different designs. The inventions of groups II and III are directed to methods that do not involve the compound of group V. To search for one of the inventions would not necessarily return art against either of the other inventions. Therefore, to search more than one of the inventions in the same application presents an undue search and examination burden.

Inventions IV and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the polypeptide can be produced by chemical synthesis rather than by culturing a host cell. To search for one of the inventions would not necessarily return art against either of the other inventions. Therefore, to search more than one of the inventions in the same application presents an undue search and examination burden.

The invention of groups II-IV are unrelated to the inventions of group VI or VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as

capable of use together and have different designs. The inventions of groups II-IV are directed to methods that do not involve the antibody of group VI or the antisense oligonucleotide of group VIII. To search for one of the inventions would not necessarily return art against either of the other inventions. Therefore, to search more than one of the inventions in the same application presents an undue search and examination burden.

The inventions of groups VII and IX-XIX are unrelated to the inventions of groups I, V, VI or VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together and have different designs. The inventions of groups VII and IX-XIX are directed to methods that do not necessarily involve the specific products of groups I, V, VI or VIII. To search for one of the inventions would not necessarily return art against either of the other inventions. Therefore, to search more than one of the inventions in the same application presents an undue search and examination burden.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise**

include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

This application contains claims directed to the following patentably distinct species: breast cancer, leukemia, lymphoma, melanoma, colorectal cancer, and lung cancer. The species are independent or distinct because each of the diseases have separate and distinct etiologic considerations.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is (571) 272-0755.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy H Bowman
Examiner
Art Unit 1635

AHB

JON E. ANGELL, PH.D.
PRIMARY EXAMINER